

Commissioner of Patents
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REMARKS

Claims 3-13 and 15-42 have been cancelled. Claims 1, 2 and 14 are pending.

Claim rejections – 35 U.S.C. § 112

Claim 14 has been rejected under 35 USC §112, second paragraph, as being indefinite. The Examiner is of the opinion that the claim is drawn to a method wherein the oligonucleotide is a randomer oligonucleotide, which does not particularly point out or distinctly claim the invention since a single oligonucleotide can not be a randomer. In order to accelerate prosecution of the present application, the Applicants wish to point out that claim 14 has been amended to no longer define that the oligonucleotide is a randomer oligonucleotide. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

Claim rejections - 35 U.S.C. § 102(b)

Claims 1, 2, 14, 17, 18, 21, 23, 27, 28, and 30-32 have been rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Krieg et al. The Examiner is mentioning that the reference of Krieg et al. teaches an immunostimulatory composition comprising nucleic acid molecules in the range of 8 to 40 base pairs in size comprising phosphorothioate stabilized oligonucleotides. In this regard, the Applicants submit that this reference is only directed to nucleic acid containing unmethylated cytosine-guanine dinucleotides (CpG) that activate the immune system. Indeed, Krieg defines "immunostimulatory nucleic acid molecule" as:

“a nucleic acid molecule, which contains an unmethylated cytosine, guanine dinucleotide sequence (i.e. "CpG DNA" or DNA containing a cytosine followed by guanosine and linked by a phosphate bond) and stimulates (e.g. has a mitogenic effect on, or induces or increases cytokine expression by) a vertebrate lymphocyte” (Column 11, Lines 10-15).

In the specifications and the examples, Krieg et al. show that CpG containing oligonucleotides have immunostimulatory activity compare to non-CpG oligonucleotides (negative controls) having no or very low immunostimulatory activity (see for examples Fig. 1C, Fig. 2, Fig. 4B, Fig. 5, Fig. 7, Table 4, Table 8, Table 9, Column 19 lines 58-64, Column 21 lines 48-51, Column 22 lines 13-16, Column 24 lines 65-67, Column 25 lines 37-40, Column 27 lines 5-12, Column 28 lines 8-11, or Column 34 lines 36-40). In addition, Krieg

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et al. teaches the therapeutic uses of immunostimulatory nucleic acid molecules containing at least one unmethylated CpG dinucleotide (Column 33 line 11 to Column 35 line 20). Krieg et al. does not demonstrate, suggest or teach the activity or the use of non-CpG oligonucleotides for the treatment of viral infections.

Furthermore, the Applicants respectfully submit that, in order to clearly distinguish the claims presently on file from the teaching found in Krieg et al., claims 1 has been amended in order to specifically encompass oligonucleotides having a sequence not comprising an immune system interacting CpG portion with the purpose of clearly distinguishing the subject matter recited in claim 1 from the teaching of Krieg et al. At paragraph [0172] in the published present application, it is discussed that there is an the advantage for the oligonucleotides of the present invention to be less toxic by interacting less with the immune system. A person skilled in the art would acknowledge that an oligonucleotide without CpG motifs would interact less with the immune system, as suggested and embodied in the present application.

In addition claim 2 has been amended to further define that the encompassed oligonucleotides comprises only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG which represent a selection of possible sequences disclosed in paragraph [0068] of the publish application.

Finally, claim 14 has been amended in order to further define that the sequence of the encompassed oligonucleotides comprises only C, A or T nucleotides, which represents a selection of nucleotides disclosed in the publish specifications at paragraph [0068].

Applicants wish to also submit that they are well aware that in order for an invention to be patentable, it must be new as defined in the patent law, which provides that an invention cannot be patented if: “(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,” or “(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States...”

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Thus, by specifying that the oligonucleotides have a sequence not comprising any CpG portion interacting with immune system; or a sequence comprising only C, A or T nucleotides; or only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG, Applicants are claiming subject matter which is not only supported and/or deduced from the present application, but that is believed to be new and inventive.

It is submitted, therefore, that the claims are now in condition for allowance. Reconsideration of the Examiner's rejections is respectfully requested.

Allowance of claims 1, 2, and 14 at an early date is solicited.

No additional fees are believed to be necessitated by this amendment. Should this be in error, authorization is hereby given to charge Deposit Account No. 19-5113 for any underpayment or to credit any overpayment.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application can be expedited.

Respectfully,

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